

In the United States District Court
for the Southern District of Georgia
Brunswick Division

FILED
U.S. DISTRICT COURT
BRUNSWICK, GA.

2008 FEB 21 A 10 18

CLERK *[Signature]*

SANDRA KAY TRICKETT, : CIVIL ACTION

Plaintiff, :

v. :

ADVANCED NEUROMODULATION :
SYSTEMS, INC., :

Defendant. NO. CV207-016

ORDER

Plaintiff, Sandra Kay Trickett, brought the above-captioned case against Defendant, Advanced Neuromodulation Systems, Inc. ("ANS"), asserting claims for strict product liability, breach of warranty, negligent design, and negligent failure to warn in connection with a medical device manufactured by Defendant. Additionally, Plaintiff asserts claims for breach of contract and intentional misrepresentation that arise from alleged representations made by Defendant's representatives.

Presently before the Court is ANS's motion for summary judgment. For the reasons set forth below, Defendant's motion will be **GRANTED IN PART** and **DENIED IN PART**.

BACKGROUND

Defendant is the manufacturer of spinal cord stimulators that are only available to patients through a physician's prescription. This action involves one of Defendant's products, the rechargeable ANS Eon Implantable Pulse Generator ("IPG"),¹ that was surgically implanted into Plaintiff.

Plaintiff suffers from chronic pain. Attempting to manage her pain, Plaintiff sought treatment from Dr. Gary Kaufmann in the fall of 2005. Dr. Kaufmann suggested the trial use of a spinal cord stimulator. After a successful trial period, in January 2006, Dr. Kaufmann implanted a permanent IPG and two lead wires² into Plaintiff's spinal column ("January Procedure").

While Plaintiff did receive some relief from the IPG, she began to experience problems. Specifically, Plaintiff reported feeling an "off/on" sensation every hour on the

¹ The IPG is a class III medical device. The FDA has approved use of the IPG to deliver low-intensity electrical impulses to selected nerve fibers as a method of pain control for certain chronic, intractable pain.

² The main components of the IPG system include the implantable pulse generator/battery, lead wire(s), an external patient programmer, and an external charging device. Metal electrodes running along the lead wires deliver electrical impulses to specific nerves in the spinal column.

hour. Further, Plaintiff was distressed at the amount of time necessary to recharge the IPG's battery.³ Plaintiff reported these problems to Dr. Kaufmann and her ANS patient programming representative Paul Dawson.

Dawson contacted Defendant's technical support team seeking to diagnose the cause of Plaintiff's "off/on" sensation. However, the exact cause could not be determined. Dr. Kaufmann and Dawson both opined that the problem was the battery and advised Plaintiff that a second surgery was needed. Plaintiff underwent a second surgery to have the pulse generator/battery replaced ("May Procedure"). The lead wires were not replaced.

After the May Procedure, Plaintiff continued to experience the "off/on" sensation and reported a new problem, an occasional jolt or shocking sensation powerful enough to bring her to her knees. Thereafter, Dr. Kaufmann consulted with ANS representatives Dawson and David Bull. Because no explanation could be found for Plaintiff's symptoms, it was proposed by Bull that

³ After the January Procedure, Plaintiff reported that she had to recharge the IPG for two hours every day.

Plaintiff undergo another revision surgery to replace the entire IPG system including the lead wires.⁴

In October 2006, Plaintiff had her IPG system replaced ("October Procedure") by Dr. Mark Gold.⁵ Plaintiff reported having the same problems after the October Procedure. Plaintiff also complained to Dr. Kaufmann that charging the battery was now taking four hours a day.

The replacement IPG remains implanted in Plaintiff, and it continues to be used to manage Plaintiff's pain. Plaintiff alleges that she has been injured by the IPG, including: the "off/on" sensations occurring every hour, occasional electric shocks, and having to recharge her IPG's battery for longer than anticipated.

Plaintiff's breach of contract claims arise from alleged statements made by Defendant's representatives regarding Defendant reimbursing Plaintiff for expenses she incurred for all three of the IPG procedures performed. According to Plaintiff, the first representation was made after the May Procedure by Dawson. Plaintiff alleges that Dawson promised that Defendant would reimburse Plaintiff

⁴ The replacement battery that was installed during the January Procedure was not replaced, but was reused in the new IPG system installed during the May Procedure.

⁵ Dr. Gold is Dr. Kaufmann's medical partner.

for her "out of pocket" costs incurred from the first two procedures.

The second alleged representation occurred prior to the October Procedure. According to Dr. Kaufmann, Bull agreed that Defendant would be responsible for certain financial costs involved with the October Procedure. Defendant's Senior Manager of Technical Support, Sabrina Goldman, sent Dr. Kaufmann a letter dated September 20, 2006 ("September Letter"), detailing those specific costs and confirming the agreement.

Upon receiving the various bills for the October Procedure, Plaintiff sent them to Defendant. After discovering those bills had not been paid, Plaintiff called Goldman on January 19, 2007. During this phone conversation, Goldman told Plaintiff that there were discrepancies with the bills. Allegedly, Goldman also denied having knowledge of the September Letter. Goldman then told Plaintiff that Defendant's legal team determined that ANS was not obligated to pay the bills, and that the bills would not be paid by Defendant. In order to prevent the bills from being sent to collection agencies,

Plaintiff made arrangements to submit the bills to her health insurance company, Humana Gold, for payment.

Prior to Plaintiff filing suit, ANS had not paid any of the bills outlined in the September Letter. On February 15, 2007, ANS paid Dr. Kaufmann the physician's fee incurred during the October Procedure. All other bills specified in the September Letter were paid by Plaintiff's health insurance.

DISCUSSION

As to Plaintiff's tort claims, Defendant's main argument for summary judgment is based on the fact that Plaintiff's experts have failed to identify a specific defect in the IPG. Defendant maintains that because of this failure Plaintiff cannot show that the IPG was the proximate cause of her injuries. As to Plaintiff's breach of contract claims, Defendant asserts that any offers made by Defendant's representatives were gratuitous offers for which ANS has no liability.

I. SUMMARY JUDGMENT STANDARD

Federal Rule of Civil Procedure 56(c) provides for summary judgment "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law." Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). Facts are "material" if they could affect the outcome of the suit under the governing substantive law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

The Court must view the facts in the light most favorable to the non-moving party, Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986), and must draw "all justifiable inferences in his favor. . . ." United States v. Four Parcels of Real Prop., 941 F.2d 1428, 1437 (11th Cir. 1991)(en banc)(internal quotation marks omitted).

The nonmoving party is required to identify specific facts which demonstrate that there is a genuine issue for trial and may not rest on the allegations or denials in its pleadings. Anderson, 477 U.S. at 248. However, in order to survive a motion for summary judgment, the non-

moving party need only present evidence from which a jury might return a verdict in its favor. If such party does so, there is a genuine issue of fact that requires a trial. Id. at 257.

II. STRICT PRODUCT LIABILITY AND NEGLIGENT DESIGN

Defendant contends that summary judgment is proper on the issues of strict liability and negligent design because Plaintiff's experts could not determine a specific defect in the product. Defendant highlights the fact that Plaintiff's experts were not able to determine the cause of Plaintiff's symptoms. Defendant argues that, due to the lack of this evidence, Plaintiff will not be able to prove "to a reasonable degree of medical certainty that the cause of the injury complained of was attributable to some defect in the device," making summary judgment appropriate. Dkt. No. 75, Def. Mot. at 10 (quoting Wheat v. Sofamor, S.N.C., 46 F. Supp. 2d 1351, 1358 (N.D. Ga. 1999)). On the issue of causation, Defendant admits that Plaintiff's "off/on" sensation is caused by a design feature of the IPG. Dkt. No. 75 at 12.

In order to recover from a manufacturer under Georgia's strict liability statute,⁶ the plaintiff must show that "the product, when sold was not merchantable and reasonably suited to the use intended and its condition when sold is the proximate cause of the injury sustained." Williams v. Am. Med. Sys., 248 Ga. App. 682, 683 (2001) (quoting Center Chem. Co. v. Parzini, 234 Ga. 868, 869 (1975)). The plaintiff is not required to show that the manufacturer was negligent. Id.

In cases that allege manufacturing defects or inadvertent design defects,⁷ "it is not necessary for the plaintiff to specify precisely the nature of the defect." He must show that the device did not operate as intended and this was the proximate cause of his injuries." Williams, 248 Ga. App. at 683 (emphasis added) (citing Firestone Tire & Rubber Co. v. King, 145 Ga. App. 840, 842 (1978)). Therefore, Plaintiff's experts' inability to

⁶ Ga. Code Ann. § 51-1-11(b)(1) provides:

[t]he manufacturer of any personal property sold as new property directly or through a dealer or any other person shall be liable in tort, irrespective of privity, to any natural person who may use, consume, or reasonably be affected by the property and who suffers injury to his person or property because the property when sold by the manufacturer was not merchantable and reasonably suited to the use intended, and its condition when sold is the proximate cause of the injury sustained.

⁷ See Banks v. ICI Americas, Inc., 264 Ga. 732, 734 n.2 (1994).

determine a specific defect in the IPG is not fatal to Plaintiff's claims.

In the instant case, there is evidence that the IPG did not operate as intended. Defendant's expert, Benjamin Tranchina, and Dr. Kaufmann both testified that the IPG is intended to be used to deliver high frequency stimulation. Further, both men testified that the IPG is designed to come on very slowly and gradually so that the patient would normally not feel the voltage surge. Dkt. No. 92, Ex. D at 36; Dkt. No. 75, Ex. A3 at 76. Tranchina also testified that while Plaintiff does use high stimulation frequencies, those frequencies are well within the IPG's program parameters. Dkt. No. 92, Ex. D at 36. In contrast, according to Plaintiff, her IPG does not perform at high frequencies. Dkt. No. 75, Ex. A1 at 204. Further, Plaintiff reports that every hour it feels like her IPG turns off and then on suddenly, not gradually. Dkt. No 92, Ex. A at 187, 324.

ANS asserts that the IPG is not defective and that the leads did not malfunction. Dkt. No. 75, Ex. A7 at 38, 80. In furtherance of its position, Defendant maintains that any malfunction in the IPG would have been capable of

being reproduced during tests performed on the IPG removed from Plaintiff, Dkt. No. 75, Ex. A7 at 4, and offers the test results of Plaintiff's old IPG as proof that there is no defect. Dkt. No. 75, Ex. A9 at 31; Ex. G; Ex. I.

In response, Plaintiff argues that test results on the IPG are not conclusive evidence as to whether the IPG was defective. In support of her argument, Plaintiff offers the testimony of Edward Palmer, an electrical engineer hired by Plaintiff to conduct tests on the explanted devices. Palmer testified that because of the condition of the IPG during testing,⁸ it would be impossible to recreate the conditions necessary to determine the exact cause of Plaintiff's symptoms. Dkt. No. 92 at 121, 128. Palmer goes on to state that while he was not able to determine a specific cause for Plaintiff's "off/on" sensation, the fact that it happens every hour on the hour, points to an electrical failure or a defect in the device. Dkt. No. 92, Ex. M at 121.

Additionally, Palmer was unable to test the lead wires because the lead wires were cut when they were removed.

⁸ Palmer indicated that the IPG was hermetically sealed in water, which made it impossible to take apart and test without destroying it. Dkt. No. 92, Ex. M at 121.

Palmer opined that because of the condition of the lead wires it would be impossible to determine whether the leads were defective. Dkt. No. 92, Ex. M at 197-203; Dkt. No. 75, Ex. A6 at 130-131. Defendant's medical expert's testimony supports Palmer's testimony. Dr. Giancarlo Barolat opined that it is difficult to determine whether a lead is defective when examining it after being removed from a body, because the lead is often damaged during removal. Dkt. No. 75, Ex. A7 at 80. Dr. Barolat also noted that leads are often cut when they are removed. Id.

Nevertheless, Dr. Barolat testified that, taking all the facts that he was given, it was his opinion that Plaintiff's symptoms were not related to the leads, and that the IPG was not defective. Dkt. No. 75, Ex. A7 at 80. Concluding that the IPG was not defective, Dr. Barolat suggested three possible causes of Plaintiff's symptoms.⁹ Dr. Barolat also opined, to a reasonable degree of medical certainty, that because Plaintiff experienced the same "off/on" sensation with three different IPG

⁹ Dr. Barolat opined that the jolting Plaintiff experienced is "most likely caused either by an abnormal reaction of her nervous system to the stimulation, by a normal compensatory stimulation to increased impedance on the lead, or abnormal sensitivity to positional change." Dkt. No. 75, Ex. A7 at 2.

systems the Plaintiff's symptom was caused by her nervous system and not the IPG. Dkt. No. 75, Ex. A7 at 68-69.

Relying on the same information submitted to Dr. Barolat, Plaintiff's medical expert, Dr. Richard Rauck, testified to the contrary. Dr. Rauck stated that it would be difficult to state to any degree of certainty that Plaintiff's symptoms were a result of an idiosyncratic reaction to the IPG. Dr. Rauck opined that the symptoms Plaintiff experienced with both devices could be attributed to a device or lead malfunction. Dkt. No. 92, Ex. L at 47, 64-65.

Defendant alleges that it is undisputed that the "off/on" feature is not a defect or malfunction of the IPG because it was designed to perform this way. Dkt. No. 75, Def. Mot. at 13. According to Tranchina, the IPG is designed to lower its voltage level to improve the efficiency of power consumption in the device. Dkt. No. 92, Ex. D at 33-34. Tranchina also stated that there was a low probability that any patient would perceive this instantaneous sensation. However, it is possible that Plaintiff could perceive this temporal event because of

the "unusually high amounts" of stimulation Plaintiff requires from her IPG. Id.

While the design that causes the "off/on" sensation may have been a planned feature of the IPG that does not preclude it from being a defect under Georgia law. In cases of intentional design defect, the risk-utility analysis applies in determining whether the product's design specifications were partially or totally defective. Banks v. ICI Americas, Inc., 264 Ga. 732, 734 (1994).¹⁰ The weighing of the risk-utility factors is generally a question for the jury. Bryan v. Hoffmann-La Roche, Inc., 262 Ga. App. 401, 409 (2003).

¹⁰ A non-exhaustive list of general factors that can be considered under the risk-utility analysis is included in a footnote in the Banks decision. It provides the following factors:

the usefulness of the product; the gravity and severity of the danger posed by the design; the likelihood of that danger; the avoidability of the danger, i.e., the user's knowledge of the product, publicity surrounding the danger, or the efficacy of warnings, as well as common knowledge and the expectation of danger; the user's ability to avoid danger; the state of the art at the time the product is manufactured; the ability to eliminate danger without impairing the usefulness of the product or making it too expensive; and the feasibility of spreading the loss in the setting of the product's price or by purchasing insurance. We note that a manufacturer's proof of compliance with industry-wide practices, state of the art, or federal regulations does not eliminate conclusively its liability for its design of allegedly defective products.

Banks, 264 Ga. at 736, n.6.

Viewed in the light most favorable to the Plaintiff, while Defendant may have evidence supporting its argument that the IPG was not defective, Plaintiff has shown that there are genuine issues of material fact in dispute on this issue. Therefore, summary judgment is denied on the issues of strict liability and negligent design.¹¹

III. FAILURE TO WARN AND THE LEARNED INTERMEDIARY DOCTRINE

Defendant maintains that, because Georgia follows the Learned Intermediary Doctrine, it had no duty to warn Plaintiff of the inherent dangers or risks associated with the IPG. Further, Defendant alleges that Plaintiff's doctors were given sufficient warnings about the symptoms of which Plaintiff complains. Plaintiff responds that Defendant failed to warn Plaintiff's physician, Dr. Kaufmann, about the risk of the symptoms experienced by Plaintiff. Specifically, Plaintiff notes the supporting testimony of Dr. Kaufmann who stated that he had not been informed that the "off/on" sensation was a risk.

¹¹ Defendant did not introduce new arguments in favor of summary judgment on the issue of negligent design. Defendant's only argument regarding negligent design was that Plaintiff's negligent design claim could not be treated as a distinct theory of recovery from her strict liability claim, and because Plaintiff could not establish the existence of a defect in the IPG, summary judgment should be granted on both issues.

Under the learned intermediary doctrine, the manufacturer of a "medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer." McCombs v. Synthes, 277 Ga. 252, 253 (2003). Ordinarily, in cases of prescription drugs and devices, "the manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result" from use. Singleton v. Airco, Inc., 169 Ga. App. 662, 664 (1984) (citations omitted). In performing this duty, the manufacturer must provide the physician with a warning that is "adequate or reasonable under the circumstances of the case." McCombs, 277 Ga. at 253.

On the issue of a warning involving the "off/on" sensation¹² Plaintiff experiences, there is evidence that ANS did not provide Dr. Kaufmann with an adequate

¹² The Court notes that ANS claims that it could not have warned any party of the "off/on" sensation and the battery recharging time because neither is an adverse effect nor a malfunction of the IPG. Defendant cites no law supporting that assertion.

warning.¹³ Dr. Kaufmann testified that he did not know the cause of this "off/on" sensation, that he had not heard of it before, and that no patient had reported feeling this sensation prior to Plaintiff. Dkt. No. 75, Ex. A3 at 31. Additionally, the Clinician's Manual includes a "Summary of Risks Identified in the Retrospective Clinical Studies" which indicates that none of the 1059 patients studied experienced "intermittent stim[ulation]." Dkt. No. 75, Def. Ex. D at 9. However, Tranchina testified that this "off/on" occurs as a result of a design feature of the product. While this "off/on" sensation had not been reported prior to Plaintiff, there is evidence that Defendant knew of that this problem may occur and did not inform Dr. Kaufmann of it being a risk. Dkt. No. 92, Ex. E at 33. Because there are genuine issues of fact in dispute as to whether the warnings regarding the "off/on"

¹³ The Court notes that Defendant submitted an additional informational guide with the title "A Guide to Spinal Cord Stimulation - A Comprehensive Guide for Spinal Cord Stimulation Candidates." Dkt. 75, Ex. P. This guide includes a warning that provides "[t]herapy may be compromised due to need to conserve battery life." Dkt. No. 75, Ex. P at 9. However, Plaintiff maintains that Dr. Kaufmann's testimony shows that he did not receive this particular informational guide and was not informed that the "off/on" sensation was a risk. Furthermore, there has been no evidence submitted suggesting that Dr. Kaufmann did in fact receive "A Guide to Spinal Cord Stimulation - A Comprehensive Guide for Spinal Cord Stimulation Candidates."

sensation were reasonable under these circumstances, summary judgment is denied.

As to the warning given to Dr. Kaufmann about the jolting sensations experienced by Plaintiff, summary judgment is granted. Defendant has submitted a clinician's manual that includes warnings about unpleasant sensations that a patient might receive when using the IPG at high stimulation outputs.¹⁴ Dkt. No. 75, Ex. D at 3-4, 6. Further, Dr. Kaufmann testified that he was made aware of the risk of overstimulation/jolting. Dkt. No. 75, Ex. A3 at 47-48. There is no evidence suggesting that the warning given to Dr. Kaufmann by Defendant, on this issue,

¹⁴ The ANS Clinician's Manual provides the following warnings regarding overstimulation/jolting:

"Lead movement - Patients should be instructed to avoid bending, twisting, stretching, or lifting objects over five pounds for six to eight weeks post-implantation. Extension of the upper torso or neck may cause lead movement and alter the stimulation field [] resulting in overstimulation or ineffective stimulation." Dkt. No. 75, Ex. D at 3.

"Postural changes - Changes in posture or abrupt movements may result in a decrease or increase in the perceived level of stimulation. Perception of higher levels of stimulation has been described by some patients as uncomfortable, painful, or jolting." Dkt. No. 75, Ex. D at 4.

"High stimulation outputs - Stimulation at high outputs may cause unpleasant sensations or motor disturbances or may render the patient incapable of controlling the patient programmer. If unpleasant sensations occur, the device should be turned off immediately." Dkt. No. 75, Ex. D at 4.

"ADVERSE EFFECTS . . . Undesirable changes in stimulation may occur over time. These changes in stimulation are possibly related to cellular changes in tissue around the electrodes, changes in the electrode position, loose electrical connections, and/or lead failure." Dkt. No. 75, Ex. D at 6.

"Lead migration, which can result in changes in stimulation and subsequent reduction in pain relief." Dkt. No. 75, Ex. D at 6.

was inadequate. Therefore, summary judgment is granted as to warning regarding Plaintiff's jolting sensation.

IV. BREACH OF WARRANTY CLAIMS

A. Implied Warranty

While Defendant's disclaimer of implied warranties¹⁵ appears to satisfy the requirements of the Georgia statute,¹⁶ because there is a dispute over whether Plaintiff actually received the disclaimer summary judgment is denied at this time.¹⁷ Furthermore, as stated above, whether there is a defect in the IPG is a disputed material fact.

¹⁵ The limited warranty provision provides, in part:

THIS LIMITED WARRANTY CONTAINS THE FINAL, COMPLETE AND EXCLUSIVE STATEMENT OF WARRANTY TERMS FOR ADVANCED NEUROMODULATION SYSTEMS, INC. EON NEUROSTIMULATION SYSTEMS, AND IT APPLIES IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED. ADVANCED NEUROMODULATION SYSTEMS, INC. DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. NO PERSON IS AUTHORIZED TO MAKE ANY OTHER GUARANTEES, WARRANTIES, OR REPRESENTATIONS ON BEHALF OF ADVANCED NEUROMODULATION SYSTEMS, INC. This limitation may not apply to you because some states and countries prohibit the limitation or exclusion of implied warranties. You may have other rights under state law not specifically addressed in this limited warranty.

Dkt. No. 75, Def. Mot. at 17.

¹⁶ Ga. Code Ann. § 11-2-316.

¹⁷ Plaintiff testified that she was unsure as to whether the exhibit was a copy of the same warranty disclaimer that she received. Defendant's counsel did not seek to authenticate the exhibit during Plaintiff's deposition. Further Plaintiff testified that she did not receive a warranty until after her surgery.

B. Express Warranty

Defendant argues that Plaintiff's breach of express warranty claim must fail because Plaintiff was not able to identify a defect in the product. In the alternative, Defendant argues that, even if the IPG is defective, Plaintiff cannot establish a breach has occurred because Defendant has performed according to the terms of the express warranty and replaced the equipment twice at no charge. Plaintiff contends that the September Letter is a modification of the express warranty, and because Defendant has not performed according to its terms, a breach has occurred.

Under Georgia law in order to establish a claim for breach of express warranty, the plaintiff is required to show the defendant was given notice of the defect and a reasonable opportunity to repair the defect. Roland v. Ford Motor Co., Inc., 655 S.E.2d 259, 264 (Ga. Ct. App. 2007). In the present case, Plaintiff did notify Defendant that the IPG was not performing properly. Defendant did abide by the terms of the written warranty and replaced certain equipment on two different occasions.

However, Defendant's express warranty provides for modification of its terms if the modification is in writing and signed by Defendant.¹⁸ On its face, the September Letter satisfies the requirements for a modification of the express warranty. The September Letter was signed by Goldman, ANS's Senior Technical Support Manager, and confirmed that ANS agreed to pay the following costs associated with Plaintiff's October Procedure: \$1,300.00 anesthesiology fee, \$2,021.00 facility fee, \$8,750.00 physician's fee. Dkt. No. 75, Ex. E. It is undisputed that ANS has only paid the physician's fee. Dkt. No. 75, Ex. J. There is evidence that suggests there was a modification of the express warranty, and a breach of that warranty. Thus, summary judgment is denied.

¹⁸ Defendant's limited express warranty provides in part:

ADVANCED NEUROMODULATION SYSTEMS, INC. DISCLAIMS LIABILITY FOR, AND SHALL NOT BE RESPONSIBLE FOR, ANY MEDICAL EXPENSES OR ANY DIRECT INCIDENTAL OR CONSEQUENTIAL DAMAGE ARISING OUT OF, OR IN CONNECTION WITH, THE USE OR PERFORMANCE OF THE SYSTEM, WHETHER SUCH CLAIM IS BASED ON CONTRACT, TORT, WARRANTY OR OTHERWISE. This limitation of liability applies to all warranty claims. No waiver or amendment of this limited warranty shall be valid unless in writing signed by Advanced Neuromodulation Systems, Inc.

Dkt. No. 75, Ex. B at 39 (underline added).

V. BREACH OF CONTRACT

Plaintiff asserts that two different representations support her breach of contract claims. First, Plaintiff alleges that Defendant breached an oral promise made by Dawson to reimburse Plaintiff for all costs associated with the January and May Procedures. Second, Plaintiff asserts that the September Letter is a contract, and that Defendant's refusal to pay the bills outlined in the letter constitutes a breach.

Defendant maintains that any recoverable damages are limited by the terms of the express warranty that requires all modifications be in writing. Therefore, Defendant argues that Plaintiff has no basis for a breach of contract claim based on Dawson's oral promise, and that Plaintiff's breach of contract claim rests solely on the September Letter.¹⁹ Further, Defendant insists that Plaintiff was not damaged by any alleged agreement because Plaintiff's insurance company paid the fees that Defendant refused to pay.

¹⁹ While Defendant's assertion that the express warranty precludes Plaintiff's breach of contract claim based on Dawson's oral representation may be correct, the Court does not address this argument because summary judgment is granted on this issue for a different reason.

Next, Defendant submits that the September Letter was a gratuitous promise unenforceable under Georgia law because it was not supported by consideration. Finally, Defendant contends that, as an evidentiary matter, the September Letter is inadmissible because it is an offer of assistance, or "an expression made on the impulse of benevolence in response to numerous attempts to assist a patient." Dkt. No. 75 at 21.

"A contract is an agreement between two or more parties for the doing or not doing of some specified thing." Ga. Code Ann. § 13-1-1. In order to establish that a contract exists under Georgia law, the plaintiff must prove three elements: the subject matter of the contract, consideration, and mutual assent to all the terms by all the parties. Roland v. Ford Motor Co., Inc., 655 S.E.2d 259, 264 (Ga. Ct. App. 2007). "There is no requirement that the contract be in writing. A contract may be enforceable even though it 'rests only in words remember by the witnesses.'" Cline v. Lee, 260 Ga. App. 164, 168 (2003) (quoting Ga. Code Ann. § 13-1-5(b)).

A. Consideration

Plaintiff alleges that Dawson made the promise to reimburse her for the costs associated with the first two procedures following a meeting with Dawson after the May Procedure. As proof of Dawson's promise to reimburse her for the "out of pocket" expenses from the January and May Procedures, Plaintiff submitted an email correspondence she received from Dawson stating "[p]lease scan and send me all bills for your surgery co pay etc. I need a record of what it has cost you 'out of pocket,' Thanks!" Dkt. No. 92, Ex. J. While the email does give credence to Plaintiff's assertion of an alleged oral contract, Plaintiff has not introduced evidence that consideration was given for Dawson's promise. Consequently, because there is not sufficient evidence to support a contractual agreement between Plaintiff and Defendant concerning the reimbursement of expenses incurred as a result of the January and May Procedures, summary judgment is granted as to this issue.

However, on the issue of the September Letter, Plaintiff has submitted substantial evidence suggesting the existence of a contractual agreement. As evidence of an agreement, Plaintiff submits that the September Letter

clearly lists the subject matter of the contract, evidences the mutual assent of the parties, and provides consideration for the promise.

As to the subject matter of the contract and mutual assent, the September Letter itself states "[t]his letter is to confirm that ANS has agreed to pay [Plaintiff] for the following costs associated with [Plaintiff's] upcoming revision procedure." Dkt. No. 75, Ex. H. Furthermore, Plaintiff,²⁰ Dr. Kaufmann,²¹ Dawson,²² and Goldman²³ all testified that there was an agreement whereby Defendant had agreed to be responsible for the fees outlined in the September Letter. Additional evidence of the agreement was submitted by Defendant in a letter addressed to Dr. Kaufmann's office dated February 15, 2007 ("February Letter"). The February Letter, signed by Goldman states

You verbally confirmed to me via telephone that back on October 17, 2006, Dr. Mark Gold (Dr. Gary Kaufmann's partner) revised and replaced [Plaintiff's] previous ANS system. You also confirmed that Dr. Gold billed [Plaintiff] a physician's fee of \$8,750.00 for this procedure. . . . ANS has agreed to cover the physician's necessary and customary surgical fees related to performance of [Plaintiff's] revision procedure. . . .

²⁰ Dkt. No. 92, Ex. A at 302.

²¹ Dkt. No. 75, Ex. A3 at 63-65.

²² Dkt. NO. 75, Ex. A8 at 79-80.

²³ Dkt. No. 75, Ex. A12 at 22-23.

Enclosed is a copy of the letter dated September 20, 2006 that ANS sent to Dr. Kaufmann which outlines the details of this agreement. Also enclosed is a check in the amount of \$8,750.00 that ANS is paying on behalf of [Plaintiff] in order to reimburse any amounts owed by her relating to the physician's fee for the revision and replacement of our product.

Dkt. No. 75, Ex. J.

Notwithstanding the above evidence, Defendant maintains that no contract exists because no consideration was given by Plaintiff for the promises outlined in the September Letter. Under Georgia law, for there to be consideration, "it is not necessary that the promisor receive anything, as loss, trouble or disadvantage undergone by the ... promisee is a sufficient consideration." Collins v. Gwinnett Bank & Trust Co., 149 Ga. App. 658, 658 (1979) (citing Whitley v. Powell, 47 Ga. App. 105, 106 (1933)).

Contrary to Defendant's assertion, there is some evidence of consideration. Plaintiff had valid health insurance at the time of the October Procedure. However, according to terms of the September Letter,²⁴ Plaintiff

²⁴ The September Letter directed Dr. Kaufmann to "please bill the [Plaintiff] for your above listed fees, which will be covered by ANS and paid by check to the [Plaintiff]. The [Plaintiff] will ultimately be responsible for paying the fees." Dkt. No. 75, Ex. J.

agreed to have the bills sent directly to her and to be personally responsible for paying the fees. Viewing this evidence in the light most favorable to Plaintiff, a jury could find that this disadvantage was adequate consideration.

B. Gratuitous Promise

In arguing that the September Letter was a gratuitous promise, Defendant cites to two cases, Thomas v. Dickson, 250 Ga. 772 (1983) and McLain v. Heard, 162 Ga. App. 780 (1982). The Court finds Defendant's reliance on these two cases unpersuasive. Thomas does not speak to the issue of gratuitous promises or breach of contract claims, and McLain is distinguishable from the present case.

In McLain, a widow agreed to pay her deceased husband's creditor because of a moral obligation. The letter was silent as to the identification of the indebtedness, the amount, rate of interest, and was not supported by consideration. McLain, 162 Ga. App. at 481. In the current case, the September Letter was not for a past debt, it was for a debt that had not yet been

incurred. Further, the September Letter was specific about the terms of the agreement, and arguably identified consideration.

C. Evidence of a Breach

"The elements of a right to recover for breach of contract under Georgia law are simply 'the breach and the resultant damages to the party who has the right to complain about the contract being broken.'" Bartholomew v. AGL Res. Inc., 361 F.3d 1333, 1339 (11th Cir. 2004) (quoting Budget Rent-a-Car of Atlanta, Inc. v. Webb, 220 Ga. App. 278, 297-280 (1996)). It is undisputed that Defendant did not comply with all the terms set out in the September Letter. Defendant has only paid Dr. Kaufmann the physician's fee. Defendant has not paid any other fee in connection with the October Procedure.

Defendant contends that the bills were not paid because there were discrepancies in the bills that Plaintiff would not help resolve. Specifically, Defendant maintains that Plaintiff was responsible for any bills over the amount agreed to in the September Letter. However, according to Goldman, Plaintiff was never told

that she would be responsible for any of the medical bills from the October Procedure. Dkt. No. 75, Ex. A12 at 20. Further, Plaintiff was not notified that there were any discrepancies in the bills until Plaintiff called Defendant more than two months after sending Defendant the bills.

D. Evidence of Damages

Defendant maintains that Plaintiff cannot demonstrate any damages resulting from the alleged breach of contract because Plaintiff's health insurance has paid the outstanding bills from the October Procedure. However, Defendant is not entitled to summary judgment for failure to prove any damages in this case, because in every action for alleged breach of contract, even if there is no actual damage, "the injured party may recover nominal damages sufficient to cover the costs of bringing the action." Ga. Code Ann. § 13-6-6; see also Capricorn Sys., Inc. v. Pednekar, 248 Ga. App. 424, 428 (2001); Don Swan Sales Corp. v. Parr, 189 Ga. App. 222, 225 (1988) (holding that the lack of evidence of harm to the plaintiff does not

constitute a viable basis for granting a motion for summary judgment).

E. Admissibility of September Letter

Defendant seeks to exclude the September Letter pursuant to Ga. Code Ann. §§ 24-3-37 and 24-3-37.1(a). Defendant maintains that the September Letter is a gratuitous offer and inadmissible because the "offer may be categorized as one of assistance, or an expression made on the impulse of benevolence in response to numerous attempts to assist a patient." Dkt. No. 75, Def. Mot. at 21.

Pursuant to the Georgia Code, "admissions or propositions made with a view to a compromise are not proper evidence" and are inadmissible. Ga. Code Ann. § 24-3-37. However, an admission of liability

contained in an offer to settle, brought about by a simple demand for settlement, is not inadmissible on the ground that such admission was "made with a view to a compromise," when there is nothing whatever to indicate that there has been any effort to compromise, and when it can not be inferred from the circumstances under which the offer was made that there has been such an effort.

Campbell v. Mut. Serv. Corp., 152 Ga. App. 493, 494 (1979) (quoting Teasley v. Bradley, 110 Ga. 497 (1900)). "There is a distinction between an offer or proposition to compromise a doubtful or disputed claim, and an offer to settle upon certain terms a claim that is unquestioned. An admission made in an offer to settle will be admissible while one made in an offer to compromise will not." Charter Mortgage Co. v. Ahouse, 165 Ga. App. 497, 497 (1983).

The evidence presented to the Court suggests that the September Letter is an admissible offer to settle. Plaintiff's doctor contacted Defendant and requested that Defendant pay for the October procedure. Dkt. No. 75, Ex. A11, 28. Defendant agreed to the request and drafted the September Letter to confirm the specific terms involved in the agreement. When the September Letter was drafted, Defendant's liability was not in dispute. See Myers v. Myers, 195 Ga. App. 529, 530 (1990) (proposal to settle administration of an estate not an offer to compromise when made outside the confines of litigation, and evidence did not reflect offer to compromise the claim for less); see also Turner Broad. Sys. Inc. v. Europe Craft Imports,

Inc., 186 Ga. App. 286, 289 (1988) (offer to pay full amount of invoices found to be offer to settle where terms were certain and claim was unquestioned at the time offer was made).

The Georgia Code also provides that "an activity constituting a voluntary offer of assistance made on the impulse of benevolence or sympathy," is inadmissible as an admission of liability. Ga. Code Ann. § 24-3-37.1. In the present case, Plaintiff insists that the September Letter was not a gratuitous promise.

There is some evidence that Defendant made the offer seeking to promote goodwill with Dr. Kaufmann and not just on the impulse of benevolence or sympathy. Dr. Kaufmann only uses Defendant's products in his medical practice. Dkt. No 75, Ex. A1 at 125. Dr. Kaufmann has implanted over thirty spinal cord stimulators in the past three years. Dkt. No. 75, Ex A3 at 6. A new spinal cord stimulator with lead wires costs approximately \$39,500. Dkt. No. 75, Ex. E. Defendant paid only Dr. Kaufmann for the October Procedure performed on Plaintiff. Dkt. No. 75, Ex. J. Therefore, whether the offer to pay "was made as a gratuity or as an admission of negligence" is a

factual issue of substantial controversy which cannot be determined as a matter of law on motion for summary judgment." White v. Front Page, Inc., 133 Ga. App. 749, 750 (1975) (citing Travelers Indem. Co. v. Erickson's, Inc., 396 F.2d 134, 136 (5th Cir. 1968)).²⁵ Summary judgment with respect to Plaintiff's breach of contract claim based on the September Letter is denied.

VI. MISREPRESENTATION CLAIM

As the basis for her misrepresentation claim, Plaintiff alleges that Defendant knowingly made false representations to Plaintiff. Plaintiff further alleges that based on Defendant's representations, Plaintiff underwent a third surgical procedure, to her financial and physical detriment. Dkt. No. 92, Pl. Resp. at 20.

Under Georgia law the necessary elements of a claim for fraud are: (1) misrepresentation by a defendant of a material existing fact; (2) with knowledge that it is false or with reckless disregard as to whether it was true; (3) with intent to induce the plaintiff to act or

²⁵ Cases decided by the Fifth Circuit prior to October 1, 1981, are binding precedent in the Eleventh Circuit. Bonner v. City of Prichard, 661 F.2d 1206, 1209 (11th Cir. 1981).

refrain from acting; (4) that is justifiably relied upon by the plaintiff; and (5) that because of such reliance, the plaintiff was damaged." GIW Indus. Inc. v. JerPeg Contracting, Inc., No. CV106-127, 2008 WL 110618, at *9 (S.D. Ga. Jan. 10, 2008). In arguing for summary judgment, Defendant focuses on only two elements of the claim, Plaintiff's reliance on Defendant's alleged statement and whether the statement was knowingly false. Dkt. No. 75 at 22.

While Dawson's email, as discussed above, does evidence an interest in ANS regarding Plaintiff's "out of pocket" expenses, Plaintiff has not introduced evidence showing that she relied to her detriment on Dawson's statements. It is undisputed that Dawson made the oral representation after the May Procedure, and after Plaintiff had already paid the "out of pocket" costs. Therefore, summary judgment is granted as to Plaintiff's claim for intentional misrepresentation regarding Dawson's promise that Defendant would reimburse Plaintiff for the January and May Procedures.

Concerning the September Letter, Defendant claims that Plaintiff cannot show that she relied on Defendant's

representation because Plaintiff stated that she would have had the October Procedure if Dr. Kaufmann had recommended it, even without the September Letter. Dkt. No. 75, Ex. A1 at 292, 293-294. However, contrary to Defendant's position, there is evidence that Plaintiff relied on the representations made in the September Letter. Bull, who initiated the drafting of the September Letter, Dkt. No. 75, Ex. A1 at 396, testified that Defendant was made aware that Plaintiff was "uncomfortable paying for anything else" in connection with another revision surgery. Dkt. No. 75, Ex. A11 at 26. Further, Plaintiff testified that she expressed to Dr. Kaufmann her need to have a letter from ANS confirming the payment agreement before she would agree to schedule the October Procedure. Dkt. No. 75, Ex. A1 at 302, 359.

As to whether the statement was knowingly false, Plaintiff has submitted evidence to show that ANS did not perform according to terms stated in the September Letter. Whether ANS intended to deceive Plaintiff at the time the September Letter was drafted is not an issue to be decided on summary judgment. "Scienter is 'peculiarly' a jury issue; it deals with the choice of what to believe

regarding a subjective state of mind seldom capable of direct proof." GIW Indus., 2008 WL 110618, at *11 (S.D. Ga. 2008). Summary judgment on Plaintiff's claims for intentional misrepresentation based on the September Letter is denied.

VII. ATTORNEYS' FEES

Defendant suggests that summary judgment is proper as to Plaintiff's claim for attorney fees because the evidence clearly indicates that there is a bona fide controversy between the parties as to Plaintiff's allegations. Moreover, Defendant claims that the evidence of record fails to demonstrate bad faith on the part of ANS, particularly in light of the lack of expert testimony specifying a defect in the IPG, and Plaintiff's refusal to cooperate to rectify the billing discrepancies following the October Procedure.

Plaintiff concedes that a bona fide controversy exists as to ANS's liability for her injuries. However, Plaintiff insists that there is sufficient evidence from which a jury could determine that "(1) ANS assumed liability for the defective condition of its products; and

(2) it unconditionally represented to [Plaintiff] that it would reimburse her for past medical bills . . . and that it would pay for [Plaintiff's] medical bills in connection with a full replacement of the medical devices." Dkt. No. 92 at 22. Further, Plaintiff submits that evidence that Defendant acted in bad faith with respect to a contract or agreement, thus the existence of a bona fide controversy as to liability is not an impediment to an award of attorney fees.

Georgia law provides for the expenses of litigation to be awarded by the jury "where the plaintiff has specially pleaded and has made prayer therefor and where the defendant has acted in bad faith, has been stubbornly litigious, or has caused the plaintiff unnecessary trouble and expense." Ga. Code Ann. § 13-6-11. It is not necessary that Plaintiff prove all three statutory grounds to justify the award of attorney fees. See Jeff Goolsby Homes Corp. v. Smith, 168 Ga. App. 218, 222 (1983) (holding that the question of whether one of the three statutory grounds have been established is for the jury to decide).

Even in cases where there clearly is a bona fide controversy as to liability or the amount of liability,

attorney fees may still be awarded if the jury finds the defendant liable and "that in addition he acted in the most atrocious bad faith in his dealing with the plaintiff." Powell v. Watson, 190 Ga. App. 375, 376 (1989). In contract actions "bad faith referred to in the code is not bad faith in refusing to pay but bad faith in the transaction out of which the cause of action arises." Jordan Bridge Co., Inc., v. I.S. Bailey, Jr., Inc., 164 Ga. App. 124, 125-126 (1982).

Regarding Plaintiff's position that ANS has assumed liability for the defective nature of its product, as stated above, there are genuine issue of material fact still in dispute on Defendant's liability and whether Defendant acted in bad faith with respect to the product liability claim. Thus, summary judgment on this issue regarding attorneys' fees is denied.

As to the breach of contract claim, when viewed in the light most favorable to Plaintiff, there is evidence that suggests Defendant acted in bad faith, which precludes granting summary judgment for Defendant. Plaintiff testified that, after receiving the September Letter, Defendant's representative directed her to check into the

hospital for her October Procedure as a "private patient" preventing the hospital from billing Plaintiff's health insurance company. Dkt. No. 92, Ex. A at 382. However, even after directing Plaintiff to assume "private patient" status, Defendant did not act on its obligations as set out in the September Letter until after Plaintiff initiated this action.

Further, other evidence suggests that Defendant "acted with some interested or sinister motive," with respect to entering into and partially performing the alleged contract, especially in light of Defendant's relationship with Dr. Kaufmann. Centre Pointe Inv., Inc. v. Frank M. Darby Co., 249 Ga. App. 782, 787 (2001). As recited above, Defendant had an established relationship with Dr. Kaufmann and stood to gain financially by continuing that relationship. Consequently, a jury could find that Defendant acted in bad faith in entering into the agreement and further in deciding only to pay Dr. Kaufmann's bill.

VIII. PUNITIVE DAMAGES

Defendant's motion for summary judgment alleges that there is no evidence of intentional wrongdoing, malice, fraud, or willful misconduct in this case. In response, Plaintiff alleges that Defendant's representations induced Plaintiff to undergo additional surgery, and relying on Defendant's representations, Plaintiff incurred additional medical expenses that Defendant refused to pay, which exposed her to financial ruin. Dkt. 95 at 24.

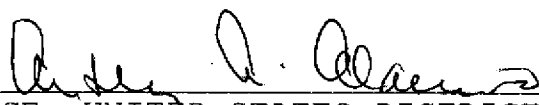
Punitive damages may be awarded in tort actions where there is clear and convincing evidence that the "defendant's actions showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of a conscious indifference to consequences." Ga. Code Ann. § 51-12-5.1. However, "punitive damages are not recoverable for breach of contract, even if the breaching party acted in bad faith If, however, there is evidence of fraud, punitive damages can be awarded, as fraud constitutes tortious conduct." Paul Dean Corp. v. Kilgore, 252 Ga. App. 587, 593 (2001). In light of the evidence discussed above, summary judgment is denied. Punitive damages may be awarded if Plaintiff prevails on her tort claims.

CONCLUSION

Having read and considered all the positions of the parties to this action, for the reasons explained above, ANS's motion for summary judgment is **GRANTED IN PART** and **DENIED IN PART**. Dkt. No. 75.

ANS's motion for summary judgment on Plaintiff's claims for breach of contract and intentional misrepresentation based on the oral representations of Dawson concerning the reimbursement of expenses incurred as a result of the January and May Procedures is **GRANTED**. As to all other grounds asserted in ANS's motion, summary judgment is **DENIED**.

SO ORDERED this 21st day of February, 2008.



JUDGE, UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF GEORGIA